UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL NO. 1456
	CIVIL ACTION NO. 01-CV-12257-PBS
THIS DOCUMENT RELATES TO:	Judge Patti B. Saris
State of Montana v. Abbott Labs Inc., et al., 02-CV-12084-PBS	
State of Nevada v. American Home Prods. Corp., et al., D. Nev. Cause No. CV-N-02-0202-ECR	

DEFENDANT IMMUNEX CORPORATION'S INDIVIDUAL MEMORANDUM OF LAW IN SUPPORT OF SUMMARY JUDGMENT AGAINST THE STATES OF NEVADA AND MONTANA

Plaintiffs the States of Montana and Nevada (collectively "Plaintiffs" or "States") have failed to produce any evidence necessary to show that defendant Immunex Corporation ("Immunex") – who has not sold or marketed any of the subject drugs for over four years – misled or even communicated with the States regarding its drugs' AWPs or acquisition costs prior to the expiration of the statutes of limitation in each State. The failure to do so bars all claims, including the unfair trade practices claims raised by each State. The evidence further shows that for nearly all the relevant period during which Immunex sold drugs, Immunex did not even report any AWPs to third-party publishers. This failure of proof is critical, as the States' allegations regarding this reporting is an essential factual predicate of its claims. Moreover, three of the five Immunex drugs that are the subject of the States'

claims are multi-source drugs, a category of drugs for which the States' expert concedes that he has not calculated or shown any damages accruing to the State based on the reporting of AWPs. These failures of proof, as to the States' general allegations and on issues which are specific to Immunex, require summary judgment in Immunex's favor on all claims.

I. BACKGROUND[1]

A. In 2002 Immunex Corporation Ceased Pricing, Marketing and Selling All of the Subject Drugs in the Nevada and Montana Complaints.

Immunex is a biopharmaceutical company formed in 1981. Immunex 56.1 Stmt. ¶ 1, Ex. B. In 2002, Immunex was acquired by Amgen Inc. ("Amgen") and is now a wholly-owned subsidiary of Amgen. *Id.* ¶¶ 2, Ex. A. In both Nevada and Montana, Plaintiffs have identified Immunex "subject drugs" as Leukine, Novantrone,[2] Thioplex, leucovorin calcium, and methotrexate sodium. State of Nevada's Amended Complaint ("Nevada Compl."), Ex A at 5; State of Montana Second Amended Complaint ("Montana Compl."), Ex. A at 24. Of those products, leucovorin calcium and methotrexate sodium are multi-source products that were available for sale from many pharmaceutical companies throughout the period of the States' claims; Thioplex (thiotepa) became subject to generic competition during this time as well. Immunex 56.1 Stmt. ¶ 3, Ex. G. Notably, many of the other companies who also sold these drugs are not defendants in this litigation. *See* Immunex 56.1 Stmt. ¶ 4, Ex. G.

In June 2001, Immunex sold its rights to market and sell leucovorin calcium and methotrexate sodium to Xanodyne Pharmacal, Inc. (not a defendant in the Montana or Nevada action). Immunex 56.1 Stmt. ¶ 5, Ex. B. In July 2002, as a condition to obtaining regulatory approval to the Amgen acquisition, Immunex sold the rights to market and sell

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[1] Immunex incorporates by reference Defendants' Joint Rule 56.1 Statement of Facts In Support of Their Motion for Summary Judgment Against the State of Montana ("Montana 56.1 Stmt.") and Defendants' Joint Rule 56.1 Statement of Facts In Support of Their Motion for Summary Judgment Against the State of Nevada ("Nevada 56.1 Stmt."). Facts specific to Immunex are set forth in Immunex Corporations Rule 56.1 Statement of Facts ("Immunex 56.1 Stmt.").

[2] Both Nevada and Montana erroneously refer to Novantrone as "Novatrone."

Leukine to Schering AG Germany (also not a defendant in either State action). *Id.* ¶ 6, Ex. A. In November 2002, Immunex entered into an agreement with Ares Trading S.A., a then wholly-owned subsidiary of Serono S.A. (not a defendant in either Montana or Nevada), pursuant to which Immunex licensed to Serono the exclusive right to market and sell Novantrone in the United States. *Id.* ¶ 7, Ex. C. In November 2002, Immunex discontinued marketing and selling Thioplex. Accordingly, since November 2002, Immunex has not priced, sold, or marketed any of the "subject drugs" in Nevada, Montana or anywhere else. The Nevada and Montana complaints were filed on March 7, 2002 and February 23, 2002, respectively. Within eight months of these filings, therefore, Immunex was not engaged in any of the conduct forming the basis of the States' Complaints.

B. The States' Evidence On Critical Liability and Damages Issues is Lacking With Respect to Immunex.

Both States allege that they believed AWPs reported to third-party publishers represented average acquisition costs for drugs, and because of that "belief" the States were unwittingly damaged by their decision to base some reimbursements on AWP. Mont. Compl. ¶¶ 7; 14-16; Nev. Compl. ¶¶ 7; 14-16. As the Defendants' joint briefs demonstrate, the evidence shows that this assertion is demonstrably false in both States.[3] But there is further proof on that point with respect to Immunex specifically. First, as of mid-1995, Immunex completely ceased any reporting of suggested AWPs to publishers. Immunex 56.1 Stmt. ¶ 8, Ex. D. Hence, the central premise of the States' Complaints regarding the

[3] As set forth in detail in the Defendants' Joint Motions for Summary Judgment against both Nevada and Montana, each State was acutely aware that AWP did not represent the actual acquisition cost for drugs in either State well before these lawsuits were filed. *See* Memorandum in Support of Defendants' Joint Motion for Summary Judgment in Montana ("Mont. Joint Memorandum") at 6-18; Memorandum in Support of Defendants' Joint Motion for Summary Judgment in Nevada ("Nev. Joint Memorandum") at 12-30. In Montana, where the applicable statute of limitations is two-years, the record shows that no later than 1995 when it participated in a Montana-specific OIG study of pharmaceutical acquisition costs, the State knew of the significant disparity between AWP and those acquisition costs. Mont. Joint Memorandum at 39-40. Consistent with testimony by the MDL Court-appointed expert Dr. Berendt that a differential between AWP and acquisition cost was phenomenon known industry-wide, the record in Nevada (where the statute of limitations is four years) also reflects the State's knowledge of the extent of that differential well before it filed its Complaint. Nev. Joint Memorandum at 38-39.

reporting of AWP is incorrect as to Immunex. Second, in 1994 and 1995, in addition to reporting AWPs to third-party publishers such as First Data Bank, Immunex *also* reported its drugs' Direct Price ("DP"). This is evidenced by the material published by First Data Bank. Immunex 56.1 Stmt. ¶ 9, Ex. G. DP is not the same as AWP. Immunex 56.1 Stmt. ¶ 10 (Gaier Declaration ¶ 45). For those years, the very data that the State claimed to rely on – information from a third-party publication – revealed on its face a differential between AWP and alternative pricing measures. And the record confirms that both Nevada and Montana had the alternative of reimbursing based on pricing benchmarks besides AWP. Mont. 56.1 Stmt. ¶¶ 2-3; Nev. 56.1 Stmt. ¶ 6-8.

Next, reflecting Immunex's lack of involvement in any purported "AWP scheme," even the States' own damages expert confirms that Immunex did not damage the States. The States' expert's calculations of damages for all five of Immunex's drugs are literally zero. Immunex 56.1 Stmt. ¶ 11. As to penalties, the States' expert has come up with a minuscule number of allegedly deceptive or false claims, but only as to Immunex's single-source drugs.[4] The three drugs for which some penalties have been calculated reveal extremely low, if any, penalties figures for Immunex. In Nevada, when applying a "sensitivity analysis" to determine the proper number of claims where penalties might have applied, Dr. Hartman calculates the low end of those penalties at $0 for Immunex because Dr. Hartman's analysis found zero false claims for Immunex. Immunex 56.1 Stmt. ¶ 12, Ex. F ("Total Statute Penalties" total $0 for Immunex). According to Dr. Hartman, in Nevada Immunex's alleged penalties amount to, at most, no more than $52,500 on a mere 7 claims, an amount that constitutes .000032% of the State's total calculation of penalties against all Defendants. *Id.* ¶ 13. Similarly, in Montana Dr. Hartman's calculation of penalties attributable to Immunex are between $33,000 and $48,000 on 11 claims, an

[4] Three of the five subject drugs at issue for Immunex – leucovorin calcium, methotrexate sodium, and (as of 2001) Thioplex – are multi-source physician-administered drugs. The States' expert Dr. Hartman testified that he has not calculated any damages or penalties for such drugs, and he has no intention to do so. Mont. 56.1 Stmt. ¶ 11, Ex. 64.

amount that is .000031% of the total calculation of penalties against all Defendants. *Id.* ¶ 14, Ex. E.

C. There is No Evidence That Immunex Ever Submitted Any Claim for Reimbursement, Much Less Did So With A "Knowing" or "Willful" Intent to Defraud.

Like all other Defendants before the Court, Immunex is not a Medicaid "provider" in either Nevada or Montana. Immunex 56.1 Stmt. ¶ 15. Unsurprisingly then, both States admit that Immunex has not submitted any claim for reimbursement to either States' Medicaid program, and that it is providers who received the States' reimbursements. Montana 56.1 Stmt. ¶ 105, Ex. 82; Nevada 56.1 Stmt. ¶ 12, Ex. 5. In both States, such providers seek reimbursement based on the methodology that Montana or Nevada Medicaid themselves establish; no Montana or Nevada regulation or law has ever required the use of AWP as part of those methodologies, or does any federal law require use of AWP by state Medicaid programs. Mont. Joint Memorandum at 3-5; Nev. Joint Memorandum at 2-4. Both Complaints are devoid of any allegation that Immunex ever even communicated with Nevada or Montana regarding the use of AWP in those States' reimbursement methodologies, much less involved itself in the claims submission process.

II. ANALYSIS

A. Summary Judgment Should Be Granted for Immunex in Montana and Nevada.

Summary judgment should be granted "if [] there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). A mere "scintilla" of evidence in support of a plaintiff's claim is insufficient; there must be evidence on which a jury could reasonably find for plaintiff. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 252 (1986). Likewise, a complete failure of proof concerning an essential element of the nonmoving party's case necessarily renders all other facts immaterial and warrants summary judgment. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986).

Since November 2002, when it effectively ceased to exist as a seller of any of the subject drugs, Immunex was not engaged in any conduct which the States disingenuously now label "fraudulent." Prior to that time, from mid-1995 forward, Immunex did not report AWPs, and the States have not produced any proof to the contrary. Likewise, in 1994 and 1995, Immunex communicated to the publishers – not the states – both Direct Price and AWPs, and so the States cannot demonstrate that Immunex is the cause of any deception or damages, because the State had the comparative price information it now claims it lacked. Not only are these claims barred substantively, because of the lack of the States' proof as to essential elements of their claims regarding Immunex, they are procedurally barred by the statutes of limitations in both States. Finally, there is no evidence in the record that Immunex's conduct satisfies the *scienter* standards in the States' Medicaid Fraud statutes or Montana's False Claims Act, a failure of proof which dooms these claims as well.

B. The States Cannot Show that Immunex Caused Any Damage After Mid-1995, When it Ceased Suggesting AWPs to the Publishers, or Before 1995 When it Reported both AWPs and Direct Price.

For claims sounding in fraud (and an alleged fraud regarding the reporting of AWP is the basis of the Montana's Unfair Trade Practices Act ("MUTPA") and Nevada's Deceptive Trade Practices Act ("DTPA") claims) there must be at least some showing that the defendant was the cause of the damages sustained by the plaintiff. *See, e.g., Rivera v. Philip Morris*, 395 F.3d 1142 (9th Cir. 2005) (to establish reliance on fraud claim in Nevada, a plaintiff must show that an alleged false representation played a material part in leading her to adopt a particular course of action); *In re Estate of Kindsfather,* 326 Mont. 192, 196-97 (2005) (in fraud-based claim the plaintiff's injuries must have been caused by their reliance on statement or action by the defendant); Mont. Compl. ¶¶ 656; 663 (Defendants have made "false and misleading statements"); Nev. Compl. ¶¶ 425; 432 (same). Both States assert that Defendants' reporting of AWPs caused them to reimburse for drugs using an AWP-based methodology, relying on the mistaken belief that AWP was

the same as a drug's actual acquisition cost. *Id.* But, as to Immunex, the Sates cannot carry their causation or damages burden.

The basic theory of the States' Complaints is that all twenty-plus defendants engaged in deceptive practices by "fraudulent reporting of fictitious AWPs." Mont. Compl. ¶ 7; Nev. Compl. ¶ 7. As to Immunex, for the vast majority of the time during which the company sold any drugs, this theory is inapplicable. From mid-1995 forward, Immunex did not report any AWPs at all. As the undisputed evidence shows, Immunex ceased "reporting" or even suggesting to the third party publishers an AWP for its products as of mid-1995. Immunex 56.1 Stmt. ¶ 8, Ex. D.[5] To the extent that a third party publisher, who the States chose not to sue, and over whom Immunex has no control, continued to publish AWPs for Immunex products does not make Immunex liable, even under the States' theory. The reporting of AWPs to publishers is an essential element of the States' cases and the basis of its claims for damages; but this is an element for which the States cannot carry their burden as to Immunex. *Celotex Corp.*, 477 U.S. at 323.

Similarly, in 1994 and 1995 third-party publishers published AWP and DP for Immunex drugs. Immunex 56.1 Stmt. ¶ 9. Both of these reported pricing benchmarks were available to the States and comparing the two made it plain that AWP was not the same thing as actual acquisition cost for Immunex's drugs.[6] So, when the States were in possession of information that confirmed their existing knowledge regarding the difference between AWP and actual acquisition cost for Immunex's drugs, the States cannot possibly show that Immunex caused the States to believe that AWP was an actual average of prices.

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[5] What Immunex communicated to the publications was a "list price." Immunex 56.1 Stmt. ¶ 8, Ex. D. The States have not alleged that Immunex's "list prices" were deceptive or fraudulent.

[6] Indeed, in Montana, the regulations setting forth the State's reimbursement methodology differentiated between AWP and DP, calling for reimbursement based on whichever benchmark produced the lowest level of reimbursement. *See* A.R.M. 37.86.1105(1); A.R.M. 37.86.1101 ("*whichever is lower*" from among the "usual and customary" charge submitted by the provider, "Direct Price," AWP less 15%, or "allowable acquisition cost . . . when the department determines that acquisition cost is lower than [DP or AWP – 15%]," or "maximum allowable cost" for multi-source drugs for which there is a Federal Upper Limit. (emphasis added)).

C. The States Cannot Show that Immunex Caused Any Damage for Multi-Source Drugs.

Three of the five Immunex subject drugs are multi-source physician-administered drugs (leucovorin calcium, methotrexate sodium, and Thioplex), a category for which the State's own expert disclaims any calculation or evidence of damage to the States. Mont. 56.1 Stmt. ¶ 11 (testimony of Dr. Hartman). This is reflected by his calculation that Immunex caused $0 in damages based on the sale of multi-source drugs. Immunex 56.1 Stmt. ¶ 12 (States' expert showing $0 damages attributable to Immunex in Nevada and Montana for multi-source drugs). Here, the States not only fail to show causation of damages, they fail to show any damages at all. The failure of the States to carry their burden of proof on damages likewise makes summary judgment proper as to these drugs. *Celotex Corp.*, 477 U.S. at 323.

D. The Statute of Limitations in Both States Bars Any Possible Claims Against Immunex.

Both Nevada and Montana allege that the Defendants, including Immunex, violated each States' trade practices act through the reporting of AWPs to third-party publishers which the States now contend were "deceptively" represented as the drugs' actual acquisition cost. Montana Compl. ¶¶ 654-667; Nevada Compl. ¶¶ 423-443. The States' lawsuits were filed in February and March, 2002 respectively. In Montana, the relevant statute of limitations is two years for all of Montana's claims, including its claims raised MUTPA. MONT. CODE ANN. § 27-2-211(1)(c). In Nevada, the statue of limitations for its claims, including its claim under the DTPA, is four years. NRS 11.190(2)(d); NRS 422.590. Both States adhere to a "discovery" rule for the operation of these statutes – as soon as a putative plaintiff through reasonable diligence can discover the facts comprising the alleged fraudulent conduct, the statute of limitations begins to run. *Osterman v. Sears, Roebuck & Co.*, 80 P.3d 435, 441-443 (Mont. 2003); *Nevada Power Co. v. Monsanto Co.*, 955 F.2d 1304, 1306-07 (9th Cir. 1992) (quoting *Howard v. Howard*, 239 P.2d 584, 589 (Nev. 1952)). Thus, in order to avoid the statute of limitations under Montana law, the State would have

had to lack knowledge of the difference between acquisition costs and AWP no later than February 2000; in Nevada that deadline would have been March 1998.

But as discussed in greater detail in Defendants' Joint Memoranda for Summary Judgment, both States were well aware of the difference (and the extent of that difference) between AWP and actual acquisition cost well before those dates. In Montana, the State was aware no later than 1995, through the results of a Montana-specific study comparing AWP to actual acquisition costs in Montana, that there was a significant difference between those two benchmarks. Mont. Joint Memorandum at 6-18. Likewise, in Nevada, by 1996 – both through federal studies the State's own purchases of drugs – the State was aware of the difference between AWP and acquisition costs. Nevada Joint Memorandum at 23-30. It is undisputed that Immunex was not engaged in any marketing or selling of its identified subject drugs after November 2002. Immunex 56.1 Stmt. ¶¶ 2-7. So, even *after* the filing of the Complaints the States' claims are barred by the cessation of all conduct by Immunex that the States claim to be in violation of either the MUTPA or DTPA.

E. Both States' Medicaid Fraud Causes of Action and Montana's False Claims Act Cause of Action and are Barred Because There is No Evidence That Immunex Meets the *Scienter* Standard of Those Statutes.

Nevada and Montana both raise claims under each State's respective Medicaid Fraud Act, complaining that Defendants' submission of AWPs to the third-party publishers who make this information available to Medicaid somehow constitutes Medicaid "fraud." Nev. Compl. ¶¶ 467-477; Mont. Compl. ¶¶ 668-679. In both States, however, these statutes require knowing or deliberate conduct on the part of the defendant in order to recover. *See* MONT. CODE ANN § 53-6-160(1), (3) ("A person who submits to a Medicaid agency an application, claim, report, document, or other information…is considered to represent to the department, to the best of the person's *knowledge and belief*[.]") ("A person is considered to have *known* that a claim, statement, or representation related to the Medicaid program was false if the person knew, or by virtue of the person's position, authority, or responsibility should have *known*, of the falsity of the claim, statement, or representation") (emphases

added); NRS 422.540 ("(1) A person, with the *intent to defraud*, commits an offense if with respect to the plan he: (a) Makes a claim or causes it to be made, *knowing the claim to be false*…(c) Makes or causes to be made a statement or representation for use by another in obtaining goods or services pursuant to the plan, *knowing the statement or representation to be false*") (emphasis added).

Relying on the same basic assertions regarding the publication of AWPs that form the basis of its Medicaid Fraud claims, Montana also raises a claim under the Montana False Claims Act. This statute also has a *scienter* provision that requires the State to show that a defendant "*knowingly* presents or causes to be presented a false, fictitious, or fraudulent claim for allowance or payment." MONT. CODE ANN. § 17-8-231(1) (emphasis added). As explained in authority interpreting the Federal False Claims Act, to satisfy that statute's *scienter* requirement requires more than "legal argumentation and possibility" that the claim or alleged behavior was false.[7] *United States v. Jamieson Science and Engineering*, 214 F.3d 1372, 1378 (D.C. Cir. 2000). As explained in *Jamieson*, a claim does not qualify as "knowingly" false if there is some dispute as to whether or not the underlying conduct violates existing law or regulation. *Id.* In both Montana and Nevada, there is no dispute that the claims suddenly labeled for litigation purposes "false" and "fraudulent" were submitted by providers (not Immunex) seeking only the reimbursement amount the States had established, in full compliance with those States' regulations.

Nevada and Montana's Medicaid fraud claims fail for the reasons set forth in the Defendants' Joint Memoranda for Summary Judgment[8], but they further fail as to Immunex

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[7] Immunex could locate no reported case law in Montana under its False Claims Act or under Nevada's Medicaid Fraud statute. "Knowledge" under the Montana False Claims Act, however, is defined identically to its definition under the Federal statute. *Compare* MONT. CODE ANN. § 17-8-402(4) ("(4) "Knowingly" means that a person, with respect to information, does any of the following: (a) has actual knowledge of the information; (b) acts in deliberate ignorance of the truth or falsity of the information; or (c) acts in reckless disregard of the truth or falsity of the information.") *with* 31 U.S.C. § 3729(b) (same).

[8] What is true for all Defendants is, of course, true for Immunex. It is not a "provider" as contemplated by either of these statutes and it has never submitted a claim for reimbursement to either Montana or Nevada Medicaid. Immunex 56.1 Stmt. ¶ 15.

because the States have set forth no evidence that Immunex acted at any time with an "intent to defraud" in connection with submission of Medicaid claims in Nevada, or that it "knowingly" presented any false claims in Montana. Without any proof on this critical *scienter* element, these claims fail with respect to Immunex. *Celotex*, 77 U.S. at 323. There is nothing in the record – no demonstrably false claim form signed or submitted by Immunex, no misleading communication between Immunex and the States regarding AWP, no admission or evidence that Immunex sought to deceive the States – which even comes close to satisfying the necessary *scienter* element.[9]

III. CONCLUSION

For all the foregoing reasons, Immunex respectfully requests that the Court grant summary judgment against Nevada and Montana on all of their claims with respect to Immunex.

[9] As to Montana's False Claims Act, all that the State can proffer is "legal argumentation" that an attenuated non-provider like Immunex can somehow "knowingly" violate the statute when a provider submits a claim that wholly complies with the reimbursement regulation. This is insufficient to establish the "knowing" conduct required under the Federal False Claims Act, and because the statutory language of Montana's statute is identical, those allegations are insufficient here as well. *Jamieson*, 214 F.3d at 1378. There is simply no evidence in the record that Immunex has engaged in the kind of specific, knowing conduct contemplated by these statutes, and the lack of proof demands that summary judgment be granted as to these claims.

DATED: February 8, 2007.

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CERTIFICATE OF SERVICE

I hereby certify that on February 8, 2007, I caused a true and correct copy of the Defendant Immunex Corporation's Individual Memorandum in Law In Support of Summary Judgment Against the States of Nevada and Montana to be served on all counsel of record by electronic service pursuant to Paragraph 11 of the Case Management Order No. 2, by sending a copy to LexisNexis File and Service for posting and notification to all parties.

By s/ *Kathleen M. O'Sullivan*
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